CPA CONNECTICUT PHARMACISTS ASSOCIATION

Statement Before
The General Law Committee
Tuesday, February 25, 2014

Re: Raised Bill 5262: An Act Concerning the Pharmacy Practice Act and Counterfeit Drugs

Good Afternoon Senator Doyle, Representative Baram and members of the General Law Committee. My name is Annik Chamberlin. I am a pharmacist and co-owner of Beacon Prescriptions Compounding Pharmacy in Southington, CT. We are a full retail pharmacy that also specializes in compounding custom medications including sterile preparations. I am also a member of the Connecticut Pharmacists Association and have been participating in a task force to evaluate the practice of compounding medications to ensure best practices and patient safety.

I am here today to speak on **Raised Bill 5262 An Act Concerning the Pharmacy Practice Act and Counterfeit Drugs.**

Section 1 clarifies the responsibility of the pharmacist when receiving prescriptions that state either "brand medically necessary" or "no substitution". We support those recommendations.

Section 2 creates new legislation for compounded medications. This is the section I would like to spend a few minutes sharing information from a pharmacist's perspective that will help you focus on this area.

Pharmacy compounding is the science of preparing personalized prescription medications for patients. Compounded medications are "made from scratch" – individual ingredients are mixed together in the exact strength and dosage form required for the patient. This method allows the compounding pharmacist to work with the patient and the prescriber to customize a medication to meet the patient's specific needs. The "art" of compounding medications has been the genesis of our profession dating back to ancient times. ***Sterile*** compounding is the preparation of custom medications for patients in a sterile environment to prevent contamination and maintain patient safety.

While we understand the basis of creating statutes in an attempt to prevent a tragedy such as the one that occurred in Massachusetts, we appreciate the opportunity to have a dialogue and talk about how pharmacists currently compound, and that any additional legislation is meaningful and does not create burdens and costs that adversely impact the critical work flow that compounding medication demands.

The United States Pharmacopeial (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries. USP created the standard 797as oversight and guidance to sterile compounding practice. The state currently requires sterile compounding pharmacies to comply with USP 797. After reviewing the draft of the proposed legislation we are providing comments for your consideration.

Section(b) Language in the third line states that a facility that intends to compound sterile pharmaceuticals for use in CT "for the first time..." needs clarification.

Rationale: the pharmacists think that language referring to "for the first time" should be clearer. For example; what if a pharmacy provided sterile compounding for a period of time, stopped for a few years, and then resumed. According to the current wording, this pharmacy does not meet the "first time rule." Suggestion was to say for the first time ever or within 2 years from the date of last inspection.

...please see reverse

Section (d)(2) Need to consider changing the last sentence to from a two-week supply to a 30 day supply as follows:

A sterile compounding pharmacy may prepare and maintain on site anticipatory inventory of sterile pharmaceuticals no greater than a 30 day supply calculated from the completion of compounding including the third party analytical testing per USP 797.

Rationale: Testing now takes approximately 25 days to complete. To do this for a 14-day supply becomes counter-productive and costly.

Section (e)(2) Remove the last two sentences of this paragraph.

Rationale: If the pharmacy remodels, relocates, upgrades or repairs something that requires sterile recertification....to be performed by an independent licensed environmental monitoring entity, the pharmacy should be required to "show evidence" of recertification but should not have to wait for "approval from the department" to resume sterile compounding. This could be laborious to the agents and could be problematic for the pharmacy when a simple notification or proof of recertification could suffice.

Section (g)(1)AND (2) requires notification of patients, care giver, practitioner and the department by the end of the next business day.

Rationale: There was some concern that if the product was provided to a large volume of patients that the next business day may not be enough time to. Perhaps some language could be added to state by the end of the next business day or a reasonable time period based on volume.

Section (j) First sentence should have language added to state....by the nonresident pharmacy's home state regulatory oversight agency every 2 years.

Rationale: They should be held to the same standards as resident pharmacies.

I also have some additional comments:
Suggestion: There should be language that exempts a pharmacy from this statute if they are an "outsourcing facility" and following GMP.
Suggestion: There was strong agreement that if an "outsourcing facility" is operating in our state that there should be a requirement to have a pharmacist in charge on site.
Suggestion: There should be an Advisory Board comprised of experts in both sterile and non-sterile compounding to augment the efforts of, and assist the pharmacy commission or the DCP Commissioner, in standards of practice for sterile and non-sterile compounding pharmacies.

Rationale: While USP 797 is an important guideline, interpretation is sometimes left up to individuals that may not have the experience in the standards of practice. An Advisory Board could enhance the knowledge and practical applications of the inspectors in a collaborative and productive fashion.
We support of the remaining sections of this legislation with one additional comment. Section 8(b) we would like it to read that "No person shall knowingly purchase for resale, sell, offer for sale or deliver
in any manner a counterfeit substance".

Thank you for your time in listening to the comments regarding the proposed regulations. The Connecticut Pharmacists Association and the compounding pharmacists in the state stand ready and available to continue to provide information and expertise on this issue to your Committee as needed.